

**Fig. 1A**

Mean rFGF Plasma Concentration Versus Time Post IC Administration

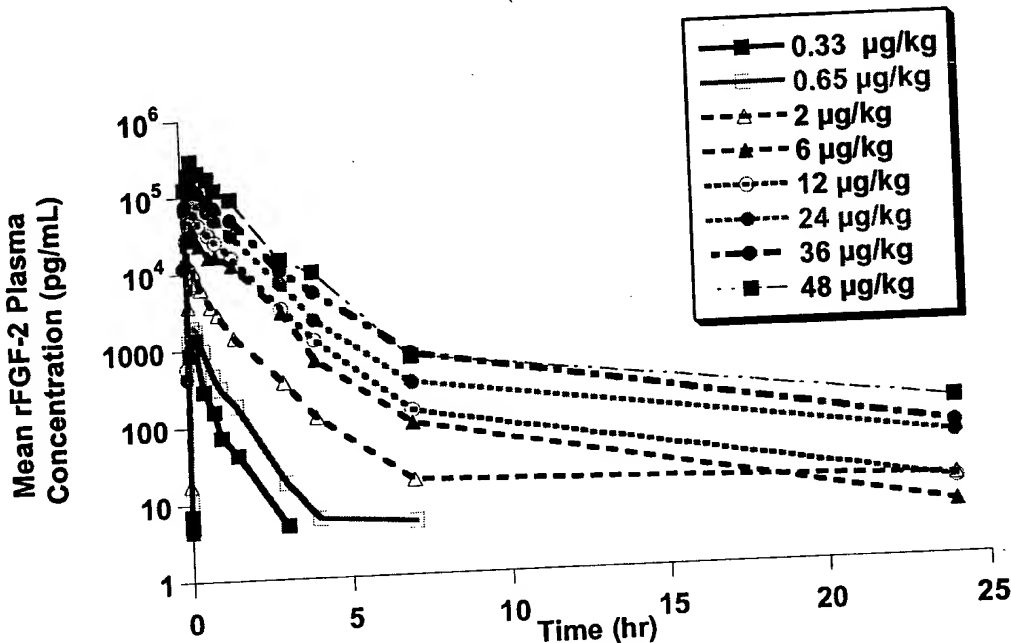
[illegible]

Fig. 1B

Mean rFGF-2 Plasma Concentration-Time Profiles Following IV Administration. Mean rFGF-2 Plasma Concentration Profile Following Administration of 36  $\mu\text{g/kg}$  IC Included for Comparison.

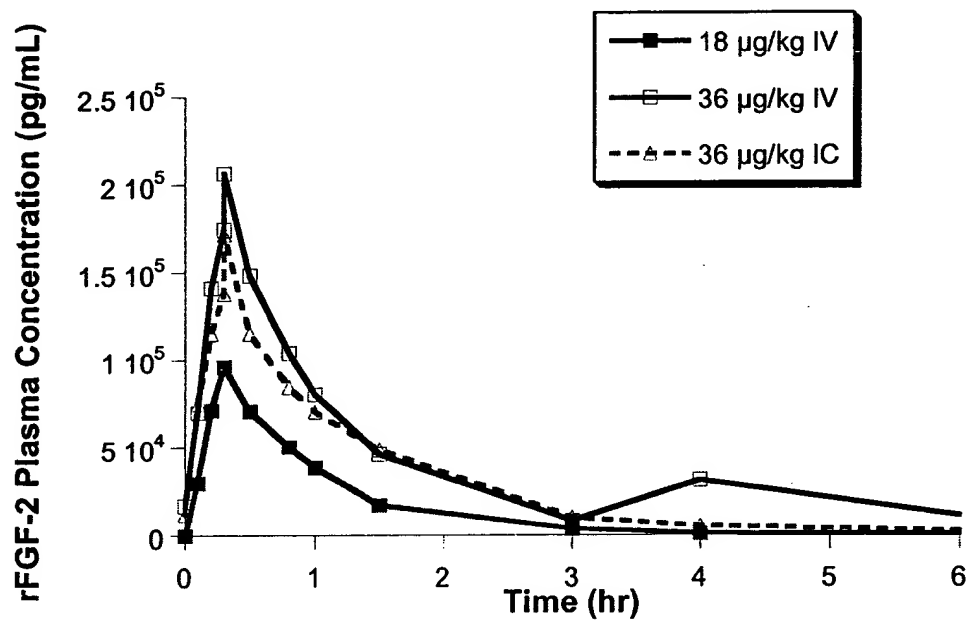


Fig. 2

Mean rFGF-2 AUC Vs Dose

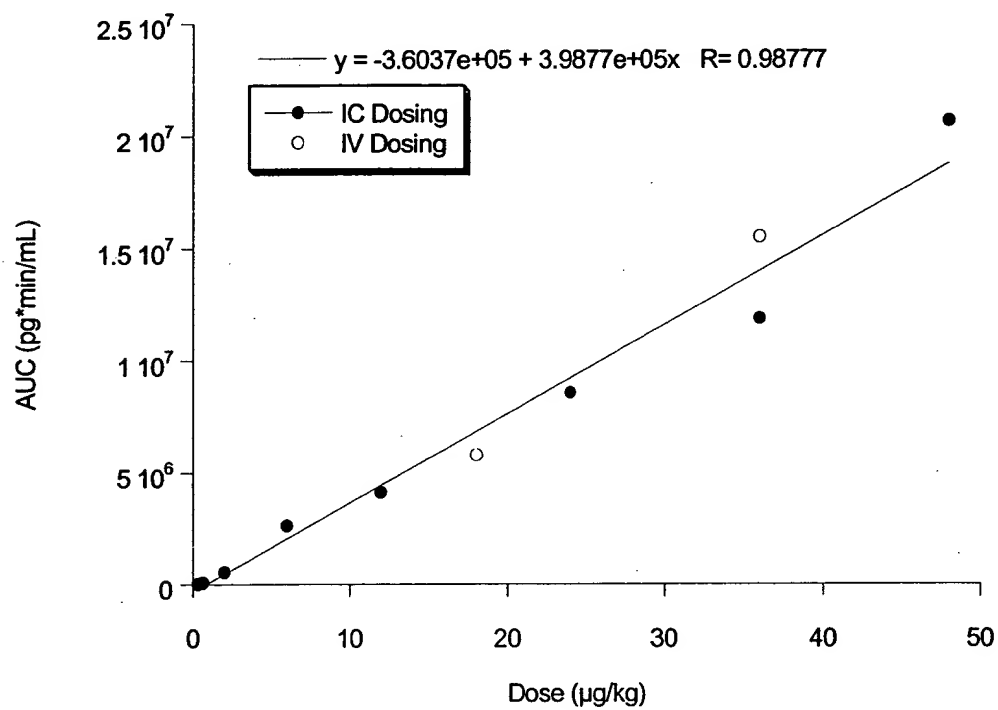
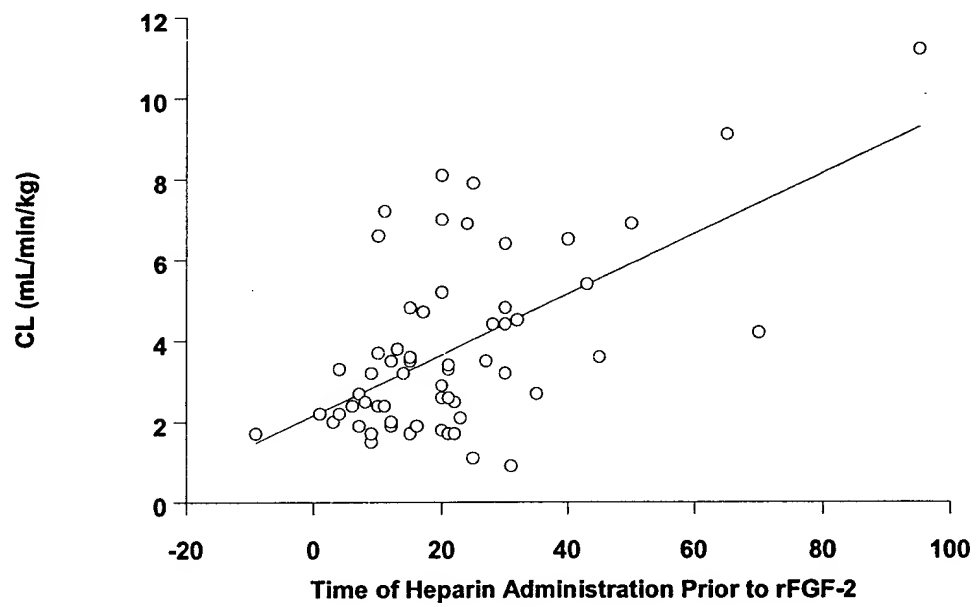


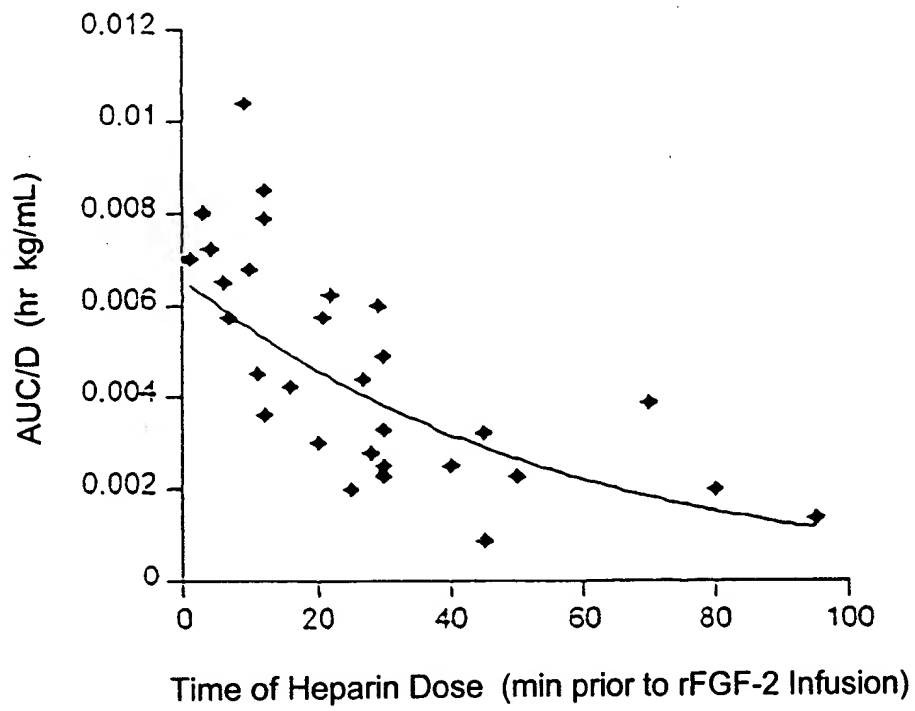
Fig. 3

Individual Patient rFGF-2 Plasma Clearance Values



**Fig. 4**

**Individual Patient rFGF-2 Dose-Normalized AUC Versus Dose in Study CS-FG001**



# *FIRST: Analysis Plan*

---

- Primary Efficacy Analysis: change in ETT at 90 days for all evaluable patients by ANOVA
  - Evaluable Patients: subjects with ETT at day 90 who were not revascularized
- Secondary Analyses:
  - ANOVA of Ranks: assigns lowest rank to patients with missing data or revascularized
  - pair-wise comparisons: each dose vs placebo, any FGF vs placebo by ANOVA and ANOVA of Ranks
- Post hoc analyses:
  - by Canadian Cardiovascular Score (CCS)
  - by angina frequency score (AFS)

# FIRST: Patient Characteristics

	rFGF-2 (ug/kg)			
	Placebo	0.3	3.0	30
Number of Subjects	86	82	84	85
Age (years)	64	63	63	62
Male sex (%)	86	84	80	86
Diabetes (%)	32	33	37	25
Dyslipidemia (%)	93	94	95	91
Hypertension (%)	77	71	68	68
Prior MI (%)	70	65	65	69
Prior CABG (%)	91	89	88	89
Prior PTCA with stent (%)	43	26	42	29
Prior PTCA w/o stent (%)	49	41	32	42
Baseline ETT time (sec)	513	527	525	514
Canadian Cardiovascular Classes II or III (%)	87	87	90	89

# FIRST: Patient Disposition

	rFGF-2 (ug/kg)			
	Placebo	0.3	3.0	30
Subjects Enrolled	86	82	84	85
Safety FU: 180 days	82	76	80	83
ETT at 90 / 180 days	82 / 75	75 / 71	79 / 74	77 / 76
Premature Withdrawal	4	6	4	2
- Death	1	1	3	1
- Adverse Event	1	2	1	0
- Withdrew Consent	1	1	0	1
- Lost to Follow-up	0	1	0	0
- Protocol Deviation / Violation	0	1	0	0
- Nonclassified	1	0	0	0
<i>Revascularized Subjects Excluded from Analysis</i>	5	5	3	6

Figure 7

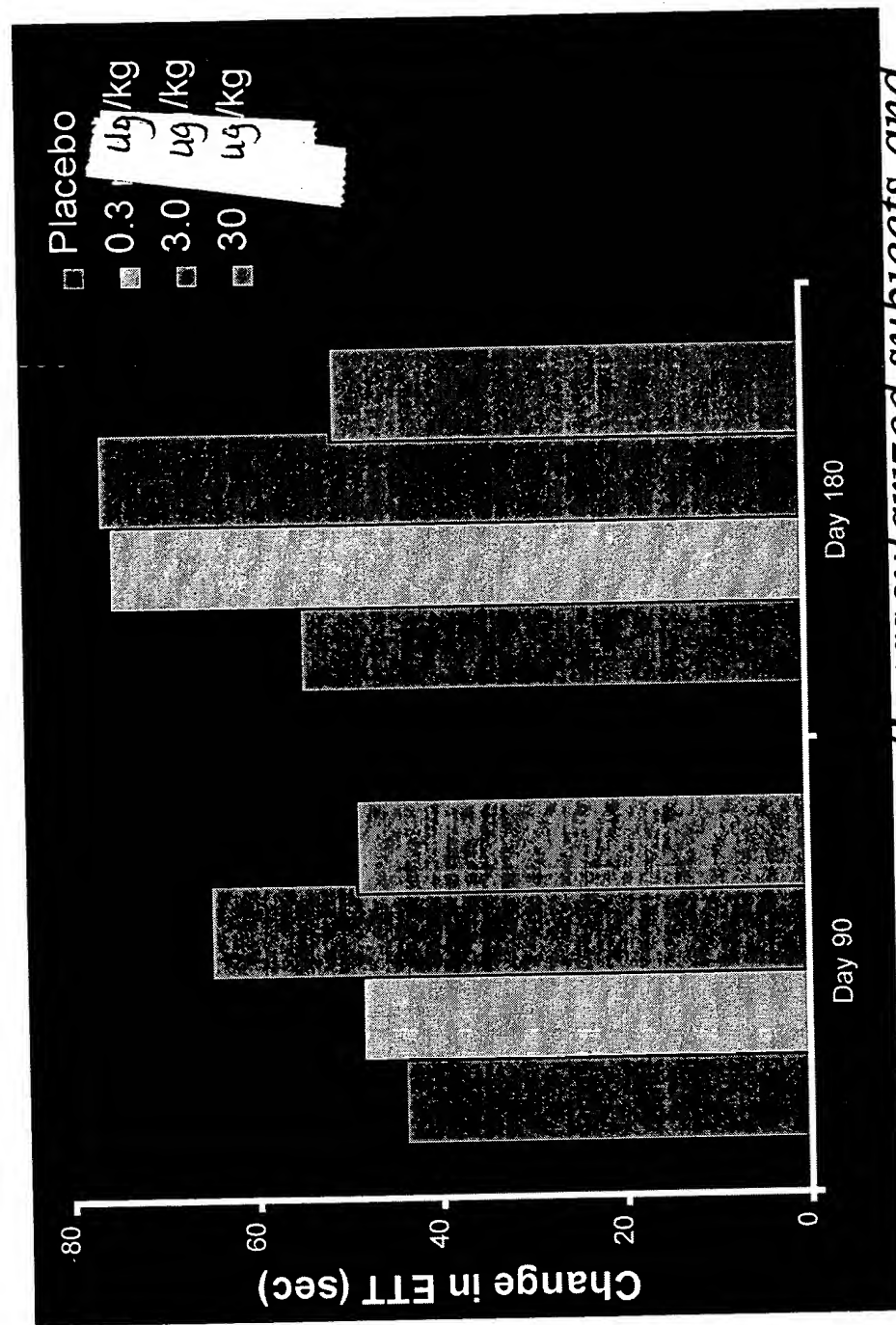


# FIRST: Safety

rFGF-2 (ug/kg)				
	Placebo	0.3	3.0	30
<b>Number of Subjects</b>	86	82	84	85
<b>All Serious Events</b>	29 (34%)	29 (35%)	22 (26%)	35 (41%)
<b>Deaths</b>	1	1	3	1
<b>Carcinoma</b>	1	0	1	1
<b>Cardiac Events</b>				
Admissions for Angina/Chest Pain	18	12	8	21
Cardiac Arrest	0	1	2	1
Myocardial Infarct	5	2	5	5
Revascularizations	5	5	3	6
<b>Laboratory Findings</b>				
Clearance: < 60 mL/min	4	0	1	3
Creatinine ≥ 2.5 mg/dL			None	
Proteinuria: > 300 mg/24 h	4	5	4	5

# Change in Exercise Time

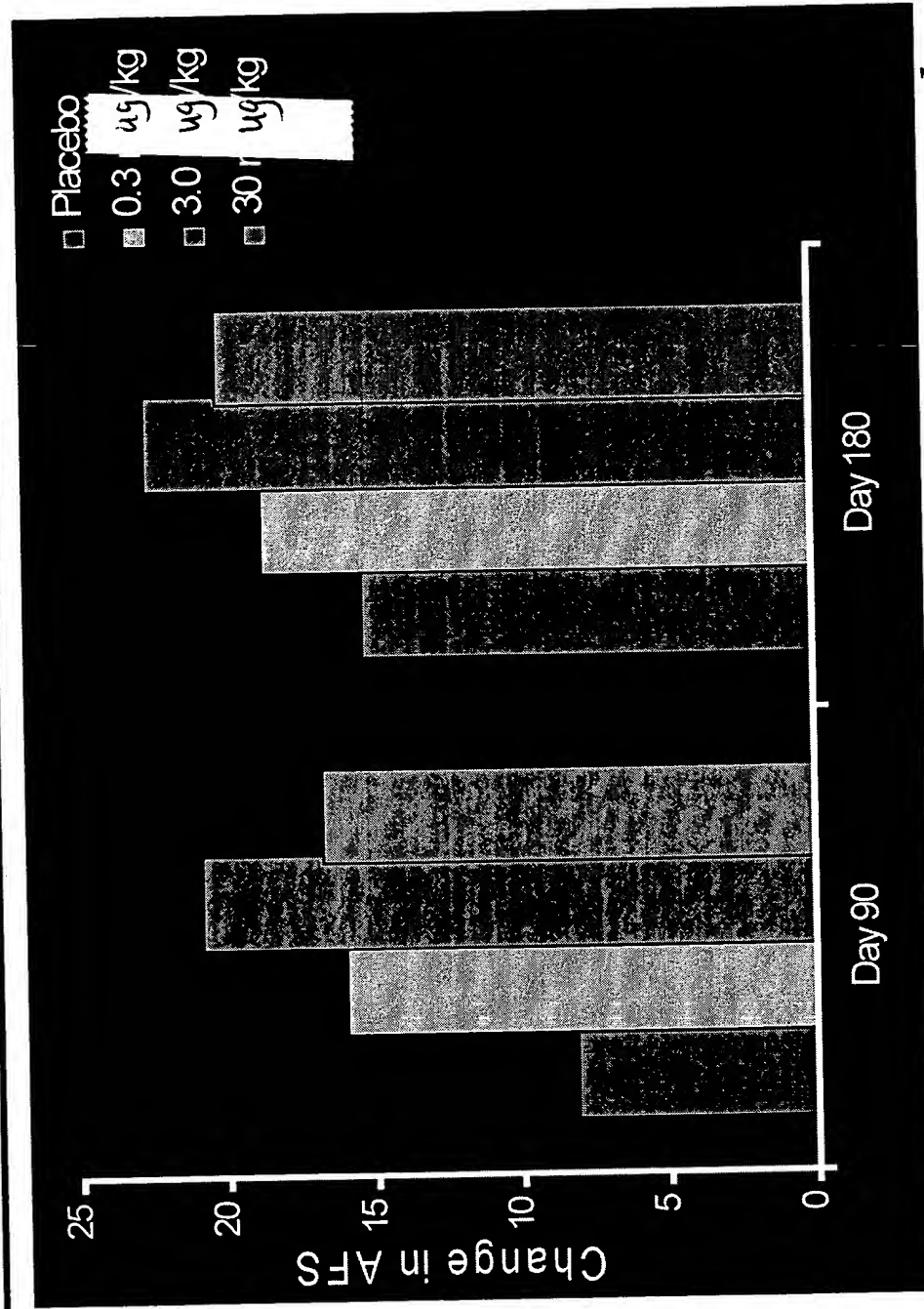
Primary Efficacy Analysis at Day 90: overall  $p = .64$



Day 180: overall  $p = 0.44$

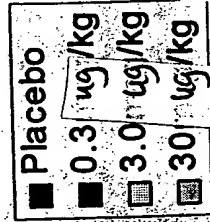
Revascularized subjects and subjects with missing ETT excluded

# Change in Angina Frequency Score

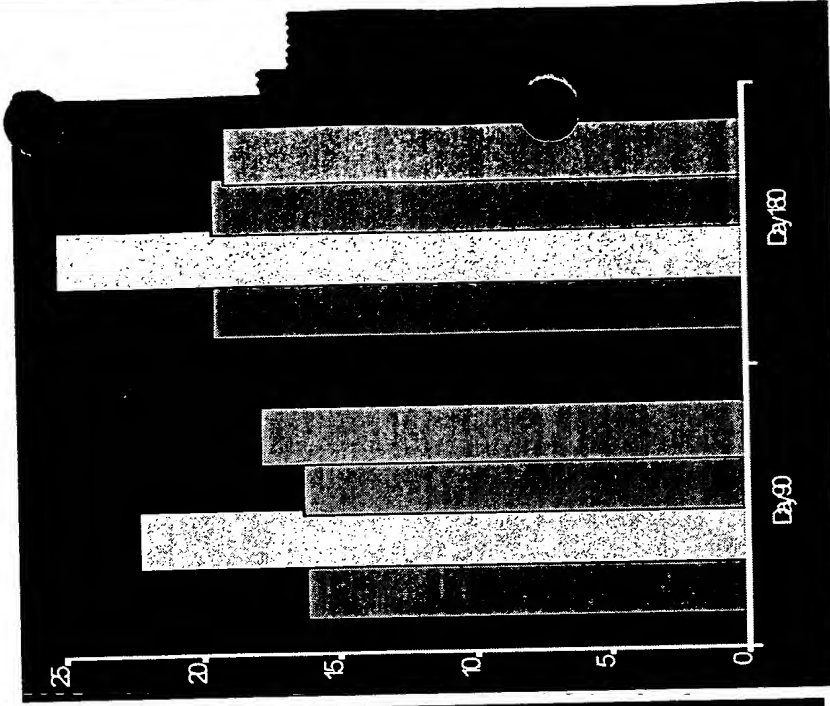
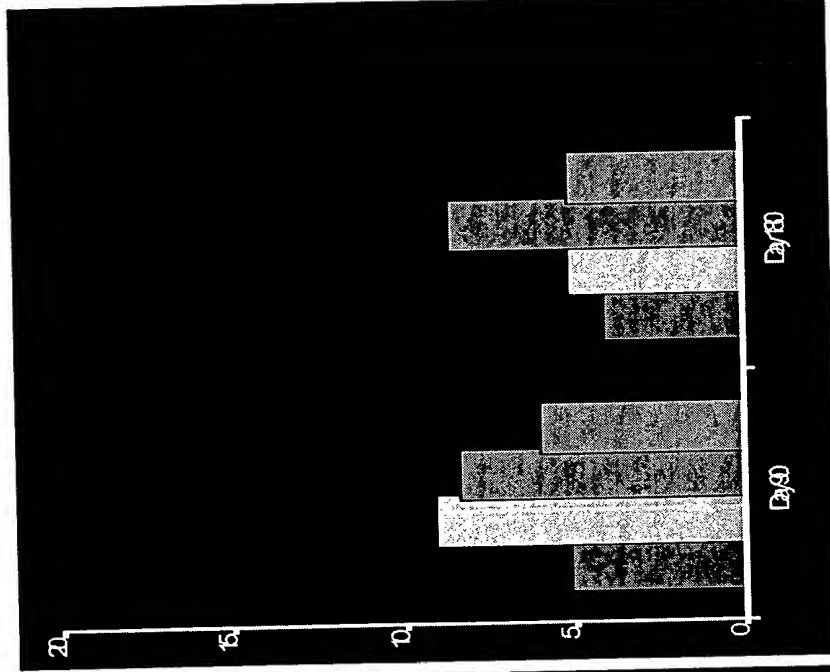
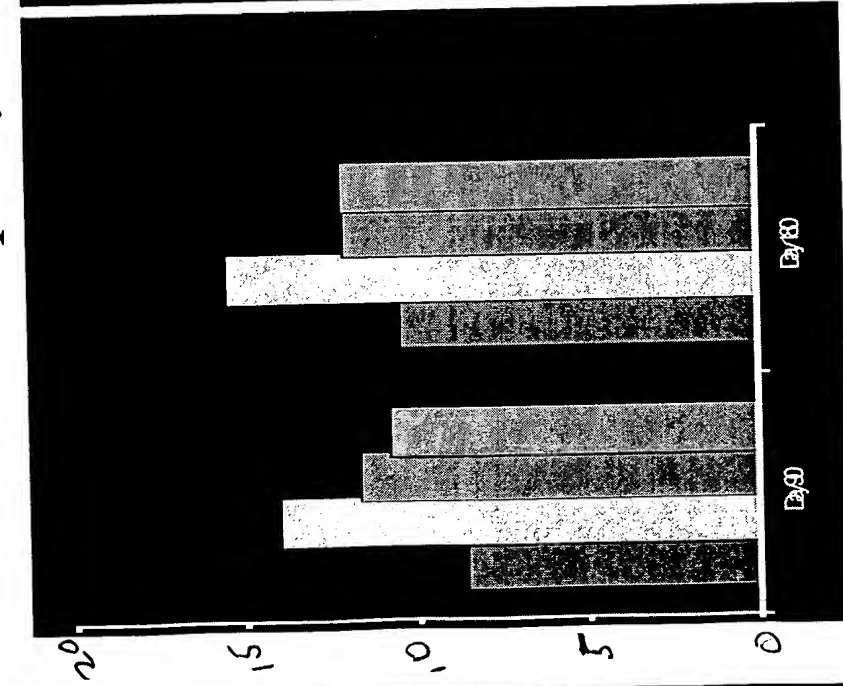


Day 90: overall  $p = 0.035^*$       *Revascularized subjects and*  
 Day 180: overall  $p = 0.38$       *subjects with no data excluded*

# Seattle Angina Questionnaire Change in Other Domains



Exertional Capacity      Treatment Satisfaction      Disease Perception



Revascularized subjects and  
subjects with no data excluded

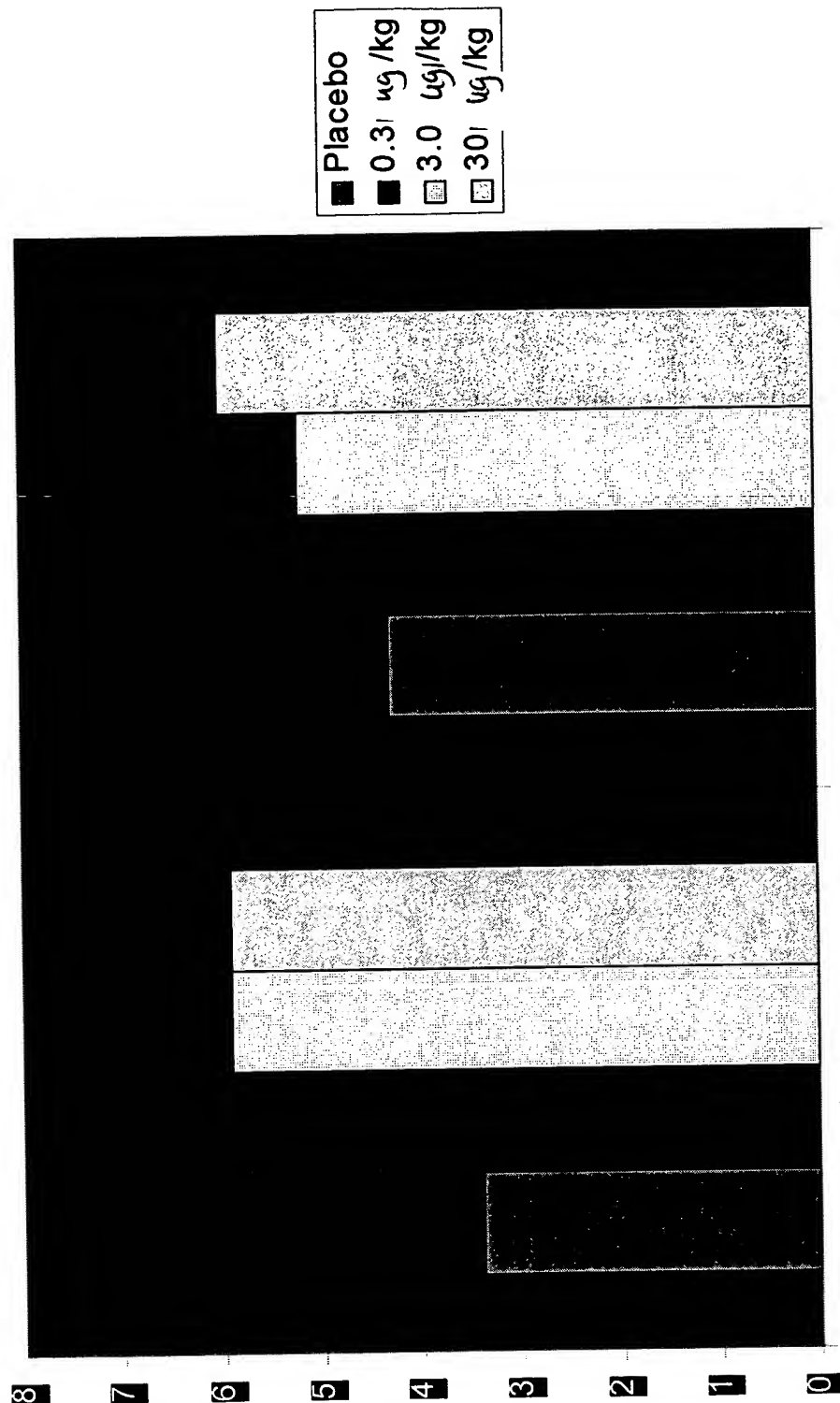
All P values > .05

Placebo  
0.3 ug/kg  
3.0 ug/kg  
30 ug/kg

Figure 11

# Change in Short Form-36

## Change in Physical Component Summary Score



Day 90 overall  $p = .21$   
 $p = .033$  for All FGF

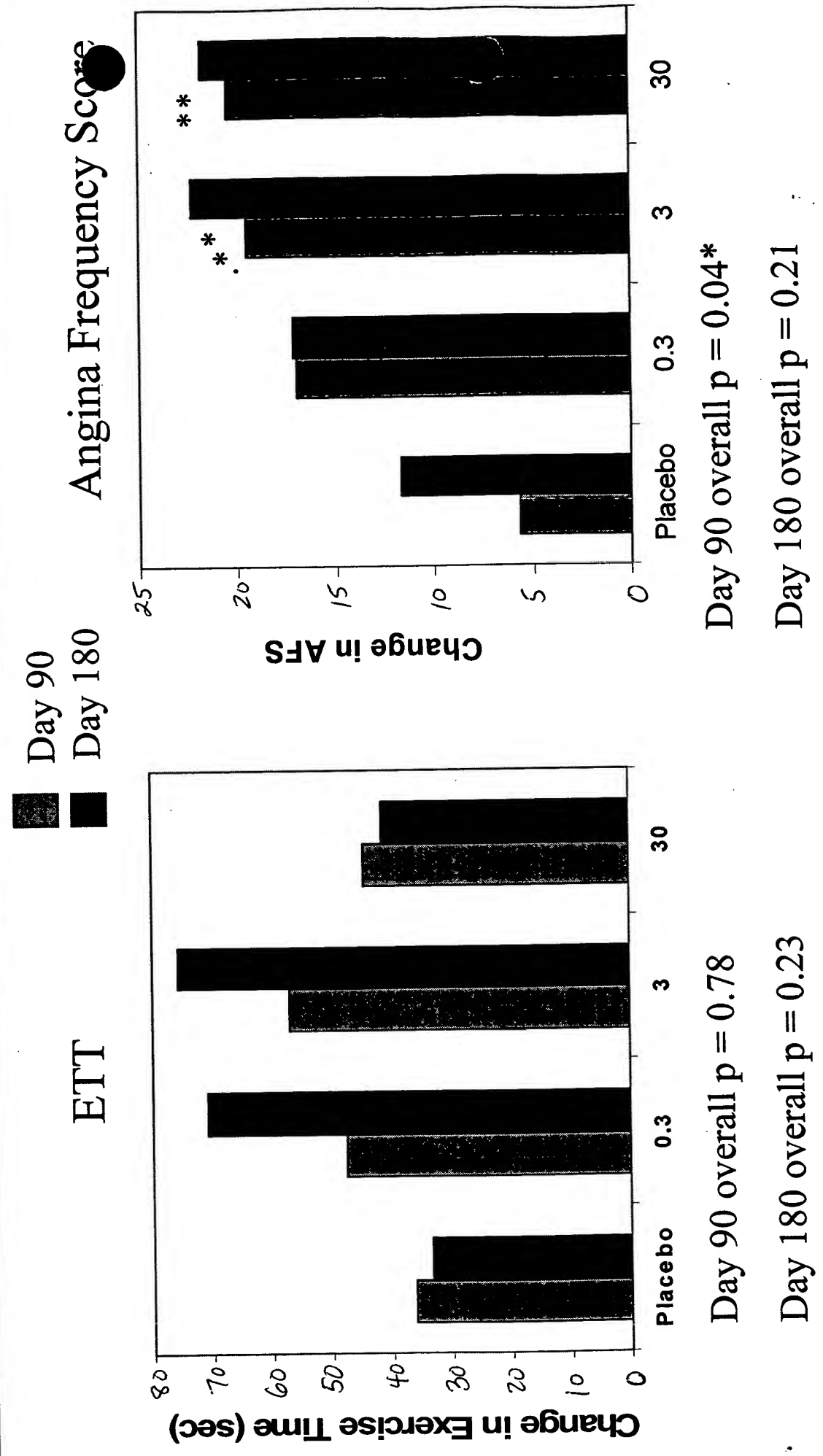
Day 180  
 Revascularized subjects and  
 subjects with no data excluded

Figure 12



Figure 13

# Stratified by Baseline CCS Class 3 or 4



# Stratified by Baseline AFS $\leq 40$

